K051872

510(k) Summary of safety and effectiveness

Applicant:

MK-dent® GmbH
Eichenweg 7B
22941 Bargteheide, Germany

Contact:

Dr. Martina Günderoth
C.R.C. Partnerschaftsgesellschaft - Hamburg Office
Christian-Koch-Weg 5
22399 Hamburg, Germany
Phone: +49 40 602 8585 / Fax: +49 40 606 79 577
Email: mguenderoth@onlinehome.de

Device Name:

MK-dent®1) Low Speed Handpieces and Acessories including Spare Parts, Tubings, and Light Power System
Models: **LS 2011, LS 2011L, LS 1011**, LS 3011L, LS 4011L, LS 5011L, LS 3011, LS 4011, LS 5011
Heads: **LS 9011**, LS 9012, LS 9013, LS 9021, LS 9021, LS 9031, LS 9111, LS 9112, LS 9211, LS 9212, LS 9213, LS 9214, LS 9215
Motors: AM 2011, AM 2012

Common Name:

Handpiece, low speed, dental

Classification Name:

Dental handpiece and accessories

Device Class:

Class I

Product Code:

76 EFB

Code of Federal Regulations:

21 CFR 872.4200

Indications for Use:

The MK-dent® Low Speed Handpieces are dental handpieces for use by a trained professional in general dentistry.

Predicate Device Name:

A-dec/W&H Synea Low Speed (K993526);
with respect to used materials: MK-dent® High Speed Dental Handpiece (K 021250, K032234)

Description of Device:

The MK-dent® Low Speed Handpieces are compatible to air and electric drives.
The handpieces are available in several versions. For example, the LS 2011L is an angled handpiece providing light through a glass optic rod, the LS 2001 has no glass optic rod, and the LS1011 is non-angled.

Substantially Equivalence - Safety and Effectiveness:

The MK-dent® Low Speed Handpiece shares virtually all specifications and design characteristics of the predicate device. It is therefore substantially equivalent to one or more dental handpieces currently marketed in the USA. The handpiece is constructed of materials of the same specifications as the predicate device to ensure biocompatibility.

Compared to the predicate the only design change refers to the division of the head from the handpiece. This change does not affect the performance but makes the handpiece more conveniant to use, as the heads may easily be exchanged.

The handpiece conforms to applicable ISO standards. The ability to repeatedly adequately sterilize the device has been confirmed by validation protocol.

Voluntary standard compliance:

- ISO Standard 7785-2: Low speed dental handpieces
- ISO Standard 1797: Shank dimensions
- ISO Standard 3964: Coupling device
- ISO Standard 27785: Water coolant
- ISO Standard 1797: Spindle strength

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 - 2005

MK-DENT GMBH
C/O Dr. Martina Gunderoth, MBA
C.R.C. – Hamburg Office
Christian-Koch-Weg 5 Hamburg,
GERMANY 22399

Re: K051872
Trade/Device Name: MK-DENT LOW SPEED HANDPIECES AND ACCESSORIES INCLUDING SPA
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EFB
Dated: June 29, 2005
Received: July 19, 2005

Dear Dr. Gunderoth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K051872_____

Device Name: MK-dent ® Low Speed Handpieces and Acessories (including Spare parts, Tubings and Light Power System),
Models: **LS 2011, LS 2011L, LS 1011** , LS 3011L, LS 4011L, LS 5011L, LS 3011, LS 4011, LS 5011
Heads: **LS 9011** , LS 9012, LS 9013, LS 9021, LS 9021, LS 9031, LS9111, LS 9112, LS 9211, LS 9212, LS 9213, LS 9214, LS 9215
Motors: AM 2011, AM 2012 Models LS 9011, LS 2011, LS 2011L and LS 1011

Indications for Use:
The device is a low speed dental handpiece for use by a trained professional in general dentistry.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051872